REMARKS

In the Final Office Action mailed January 28, 2008, Claims 35, 48-52, 54-61, 65, and 72-82 were pending for consideration. All of the claims were objected to and rejected on various statutory grounds, each of which is addressed in turn below.

By the present amendment, claims 48-50 and 72-74 have been canceled. The misspelling of polyethylene glycol in claims 35, 59, and 60 has been corrected. Claims 35, 59, and 60 have been amended to replace the terms hydroxylpropyl methylcellulose derivative and glycerol monostearate with hydroxypropyl methyl cellulose phthalate, hydroxymethylcellulose succinate, ethyl cellulose, glycerol dipalmitate, and glycerol palmitostearate. Support for the amendment can be found in the published specification on page 5, paragraph [0063] and page 6 paragraph [0064]. Further, as discussed in the interview with the Examiner on February 7, 2008, the each of claim 35, 59, and 60 have been amended to eliminate the previously presented phrase and "at least 95 wt% of the cilostazol is suspended in the composition." Claims 35, 59 and 60 were also amended to rephrase the limitation "wherein the cilostazol is released over an extended period of time" to read wherein the composition is formulated to release the cilostazol over an extended period of time, said extended period of time being between 2 and 24 hours. Support for the amendment can be found in originally filed claim 50 as well as on page 3, paragraph [0038] of the published specification. Applicants submit that no new matter has been added through this or any previous amendment of the claims.

Applicants submit that each of the amendments places the claims of the present application in condition for allowance or appeal and therefore it is respectfully requested that the amendments be entered. It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the

correctness of the Examiner's rejection. Accordingly, Claims 35, 51-52, 54-61, 65, and 75-82 are pending for consideration in the present application. Applicants respectfully submit that the present claims are allowable over the cited reference, and that the rejection in view thereof is now moot.

Claim Objections

The Examiner objected to claims 35 and 60 for having minor grammatical errors. The errors cited the Examiner have been amended as shown set forth above.

35 U.S.C. 101 Rejections

Claims 35, 48-52, 54-61, 65, and 72-82 were each rejected under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter. Specifically, the Examiner has alleged that it is unclear whether the claims are intended to encompass a product or a process. Without conceding the correctness of the rejection, Applicants have amended the claims in accordance with the agreement with the Examiner during the interview on February 8, 2008. Specifically, the claims were amended to read "wherein the composition is formulated to release the cilostazol over an extended period of time, said extended period of time being between 2 and 24 hours." Applicants submit that the presently pending claims are in compliance with § 101 and respectfully request that this rejection be withdrawn.

35 U.S.C. 112 Rejections:

Claims 35, 47-52, 59, and 72-74 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement with respect to the terms 1)

"hydroxypropylmethylcellulose derivatives" and 2) "glycerol monostearate" as well as the phrase 3) "at least 95 wt% of the cilostazol suspended in the composition." As described above, the Applicants have amended Claims 35, 59 and 60 as discussed in the interview of February 8, 2008 to replace the disputed terms with specifically enumerated hydroxypropylmethylcelluloses and specific glycerol fatty acids or fatty alcohols. Support for the claims is set forth above. The disputed phrase "at least 95 wt% of the cilostazol suspended in the composition" has been removed from the rejected claims. Applicants assert that the present amendments to each of the rejected independent claims provides ample written description as required under 35 U.S.C. §112, first paragraph, and respectfully request that each of the rejections be withdrawn.

35 U.S.C. § 103 Rejections:

The Examiner has rejected Claims 35, 42-52, 54-56, 59-61, 65-69, 75-79, and 82 under 35 U.S.C. § 103(a) as being allegedly unpatentable over the U.S. Patent No. 5,891,469 to Amselem et al. (hereinafter "Amselem") patent in view of The Merck Index (Eleventh Edition, Monograph 2277, 1989; pages 353-354). Applicants have amended each of claims 35, 59, and 60 to include that limitation found in previously pending dependent claims 50 and 74, namely that the "extended period of time" is between 2 and 24 hours.

Amselem teaches a solid dry coprecipitate of lipophilic active ingredients and tocopherol polyethyleneglycol succinate (TPGS) which is formed when the active ingredient is co-melted with the TPGS. The coprecipitates can be incorporated into oral dosage forms to provide improved release of the active agent in vitro and enhanced oral bioavailability. However, Amselem does not teach delivering cilostazol, or any other active agent, over an extended period of time. In fact, all of the release profiles taught by Amselem show immediate release of the

active agents. In the Final Office Action, the Examiner stated the following with respect to release of cilostazol over an "extended period of time:"

> ...[B]ecause neither the claims rejected herein nor the specification provide any quantification of the amount of time over which a particular amount of active agent of the formulation is intended to be released such that it would have been clear as to what amount(s) of time and amount of active agent released would have been tolerated by the claims. Furthermore, Applicant defines the phrase "extended release" relative to the phrase "immediate release" but gives no indication as to what type or degree or rate of release is encompassed by the phrase "immediate release in view of the fact that "immediate release" is defined as "release of a drug at a rate which is not significantly modified by the method of drug formulation." Absent such indication, it is herein noted that the length of time over which the formulations of Amselem et al. release the lipophilic agent meets this limitation....

The Examiner further relies on Figures 1 and 2, which disclose the release 60% to 80% in vitro of dexanabinol into simulated gastric fluid in less than 20 minutes as being release over an "extended period of time". As discussed with the Examiner in the interview, the release plateaus after the initial release because the solubility of the drug is maxed after the initial release.

As discussed in the interview with the Examiner on February 8, 2008 and as detailed above, each of the pending independent claims 35, 59, and 60 has been amended to include the limitation that the "extended period of time" over which the cilostazol is released is between 2 and 24 hours. Such a limitation clearly delineates the period of time over which the cilostazol is released. Further it is clear that Amselem does not teach a formulation containing cilostazol, or any other active agent, which provides for release of cilostazol over an extended period of time

of 2-24 hours. As would be well known to one of ordinary skill in the art, the release profiles taught in Amselem are all immediate release and clearly provide release in very short amounts of time of 20 minutes or less. As such Amselem fails to teach each and every element of the presently pending claims, namely the release of cilostazol over an extended period of time of from 2-24 hours. Therefore it is respectfully requested that the Examiner enter and allow the presently amended claims.

As a reminder of the discussion held with the Examiner in the interview regarding the novelty and inventive nature of the present invention, Applicants wish to draw the Examiner's attention to the discussion in the originally filed specification regarding existing cilostazol immediate release formulations and the negative side effects associated with the administration of such formulations. Specifically, the discussion of such formulations can be found on page 1, paragraphs [0002]-[0004] and page 4, paragraph [0049]. Such teachings are relevant in that they discuss the importance and long felt need of a cilostazol formulation which can deliver the drug in a therapeutically effective manner over an extended period of time thereby overcoming and eliminating many of the negative side effects traditionally associated with cilostazol administration.

CONCLUSION

In view of the foregoing, the Applicants believe that Claims 35, 51-52, 54-61, 65, and 75-82 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 28th day of April, 2008.

Respectfully submitted,

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